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UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

| | | |
|------------------------------------|---|------------------------------------|
| MARY KAREN MORETTI, |) | CASE NO. 2:08-CV-00396-JCM- |
| Plaintiff, |) | (GWF) |
| v. |) | |
| PLIVA, INC., and TEVA |) | |
| PHARMACEUTICALS, USA, INC., |) | |
| Defendants. |) | |

TO THE HONORABLE JUDGE JAMES C. MAHAN:

Plaintiff Mary Karen Moretti hereby submits a proposed order for the below captioned motions upon which this Court has previously ruled. The order submitted on behalf of Defendant, Pliva, misstates certain facts, and fails completely to address Defendants' Motion to Dismiss Based on Federal Preemption, which the Court also determined at the same hearing. Plaintiff proposes that the Court issue an Order containing the following language:

PROPOSED

ORDER (1) GRANTING DEFENDANTS' JOINT MOTION FOR SUMMARY JUDGMENT [DOC. 206]; (2) DENYING DEFENDANTS' JOINT MOTION TO DISMISS BASED ON FEDERAL PREEMPTION [DOC. 198]; AND (3) DENYING PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT [DOC.196]

This matter came before the Court on (1) Plaintiffs Motion for Partial Summary Judgment [Doc. 196]; (2) Defendant Teva Pharmaceuticals USA, Inc. and PLIVA, Inc.'s Joint Motion to Dismiss Based on Federal Preemption [Doc. 198]; and (3) Defendant Teva Pharmaceuticals USA, Inc., and PLIVA, Inc.'s Joint Motion for Summary Judgment [Doc. 206]. The motions were fully briefed by the parties, and an oral hearing was conducted by the Court on July 26, 2010. After a review and consideration of the briefs, authorities and the oral argument of counsel, the Court denies Plaintiff s Motion for Partial Summary Judgment, denies Defendants' Joint Motion to Dismiss Based on Federal Preemption, and grants Defendants' Motion for Summary Judgment for the reasons that follow.

I. FINDINGS OF FACT

1. Plaintiff originally filed her Complaint in the United States District Court for the District of Minnesota on September 7, 2007.

2. The Complaint alleges that Plaintiff, Mary Karen Moretti, suffered injuries as a result of ingesting the drug metoclopramide manufactured by defendants Teva Pharmaceuticals, USA, Inc. and Pliva, Inc.
3. The original complaint also asserted liability against the manufacturers of the brand name version of metoclopramide, Schwarz Pharma, Inc. (“Schwarz”) and Wyeth, Inc. (“Wyeth”), although Plaintiff did not ingest metoclopramide manufactured by these entities.
4. Defendants subsequently answered and moved to transfer venue pursuant to 28 U.S.C. § 1404. On March 17, 2008, the District of Minnesota granted the motion. This Court received the transfer on March 21, 2008.
5. Following transfer to this Court, Wyeth and Schwarz moved for summary judgment on all claims asserted by Plaintiff against them. On March 20, 2009, this Court granted Wyeth and Schwarz’s Motion for Summary Judgment, and dismissed them from the action [Doc. 148].
6. Following the Dismissal of Wyeth and Schwarz, Plaintiffs filed a Motion for Partial Summary Judgment alleging that Defendants had breached a duty owed to Plaintiff as a matter of law. [Doc. 196].
7. Defendants Pliva and Teva thereafter filed a Joint Motion to Dismiss Based on Federal Preemption [Doc.198] and a Joint Motion for Summary Judgment asserting various arguments. [Doc. 204].
8. After the filing of Defendants’ motions, Plaintiff settled her claims against Teva, and on June 22, 2010, the Court entered an order dismissing Teva from the action and leaving Pliva as the sole defendant. [Doc. 233].
9. Plaintiff asserts numerous claims against defendant, including strict products liability, breach of warranty, negligence and fraud. All of these claims arise from plaintiff’s allegations that

the label accompanying the metoclopramide ingested by Mary Karen Moretti was false or misleading.

10. The label that accompanies Pliva's metoclopramide products was, at all times relevant to this lawsuit, approved for use by the Federal Food and Drug Administration. Furthermore, under the FDA's regulatory scheme, Pliva was required to copy the label of the Reference Listed Drug for metoclopramide.

II. CONCLUSIONS OF LAW

1. Plaintiff has not opposed the granting of summary judgment in favor of Pliva on the following counts: Violation of the Minnesota Deceptive Trade Practices Act (Count 7); violation of the Minnesota False Statement in Advertising Act (Count 8); violation of the Minnesota Prevention of Consumer Fraud Act (Count 9); intentional infliction of emotional distress (Count 10); and negligent infliction of emotional distress (Count 11). In addition, this Court previously has held that Plaintiff's claims for violations of Minnesota trade practice and consumer protection laws are not viable because they do not exist under Nevada law. Findings of Fact, Conclusions of Law and Judgment on Wyeth and Schwarz Pharma, Inc.'s Motion for Summary Judgment [Doc. 148].

2. This Court has carefully reviewed and considered the memoranda filed by Pliva and Plaintiff in support of and against the various motions pending before it, and the arguments of counsel at the hearing on July 26, 2010. The Court concludes that despite the label given to the particular claims against Pliva, all of the claims arise from Plaintiff's allegation that Pliva's metoclopramide label was inadequate or misleading.

3. The Court finds that there is no genuine issue of material fact that Pliva was a manufacturer and seller of a generic version of metoclopramide and that Pliva manufactured and

sold its generic version of metoclopramide pursuant to an Abbreviated New Drug Application approved by the United States Food and Drug Administration (the “FDA”) on February 3, 1988. The Court further finds there is no genuine issue of material fact that (1) the labeling (also known as the package insert) for Pliva’s metoclopramide met the applicable statutory and regulatory requirements of being the same as the labeling for the Reference Listed Drug, Reglan; (2) the labeling was approved by the FDA; and (3) the labeling warned that tardive dyskinesia was a risk of metoclopramide use.

4. The Court concludes that as a result, the label and warnings that accompanied the metoclopramide ingested by plaintiff were adequate as a matter of law. Since Pliva provided an adequate warning for its metoclopramide, Plaintiff cannot recover against Pliva upon any claim which is based on the inadequacy or inaccuracy of the label. As referenced above, regardless of how Plaintiff has pled her claims, all of them are based in the allegation that the label accompanying Pliva’s metoclopramide was inaccurate or inadequate. As a result, all claims asserted against Pliva must be dismissed.

5. Congress has entrusted the FDA with ensuring that drugs are safe and effective for their labeled uses. *See* Drug Amendments of 1962, Pub. L. No. 87-781, §102(b), 76 Stat 780, 781 (1962) (codified as amended at 21 U.S.C. §355(b)). The regulatory oversight performed by the FDA recognizes that the use of any drug entails some risk and that marketing approval should rest on the FDA’s scientific determination that a drug’s overall health care benefit outweighs its risks. *See* S. Rep. No. 87-1744, at 15 (1962), *as reprinted in* 1962 U.S.C.C.A.N. 2884, 2891-92 (observing that for very risky drugs, “the determination of safety is, in the light of the purposes of the new drug provisions, considered by [FDA] to be inseparable from consideration of the drug’s effectiveness”); Requirements on Content and Format of Labeling for

Human Prescription Drug and Biological Products, 71 Fed.Reg. 3922, 3934 (Jan. 24, 2006), (“Under the Act and FDA Regulations, the agency makes approval decisions based . . . on a comprehensive scientific evaluation of the product’s risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling.”) (citation omitted)). Balancing risks against benefits for particular prescription drugs, dosages, and methods of administration thus has been the central task of the FDA for decades.

6. To obtain FDA approval of a new prescription drug, a generic manufacturer must submit an Abbreviated New Drug Application (“ANDA”). *See generally* 21 U.S.C. §355, 21 C.F.R. 314.94. As part of its ANDA, a generic drug manufacturer must certify that, except for minor changes in the label not at issue here, the label for its drug is “the same as” that of the reference listed drug. 21 C.F.R. §314.94(a)(8)(iii). As a requirement for initial approval of a branded drug, the manufacturer is required to submit to the FDA information establishing that the drug is safe and effective “for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof before FDA will approve it for distribution and marketing. 21 U.S.C. §355(d)(1). A generic manufacturer is therefore entitled to rely on the FDA’s determination that the labeling for the drug is adequate when generating the label for its generic product.

7. The review and approval of a drug’s labeling therefore is a critical means through which the FDA carries out its risk-benefit analysis. *See* New Drug and Antibiotic Regulations, 50 Fed. Reg. 7452, 7470 (Feb. 22, 1985) (“Drug labeling serves as the standard under which FDA determines whether a product is safe and effective.”); *see also* FDA, *Guidance: Drug Safety Information – FDA’s Communication to the Public* 7 (Mar. 2007), available at <http://www.fda.gov/cder/guidance/7477fn1.pdf> (FDA-approved drug product labeling is the

primary source of information about a drug's safety and effectiveness..."). For this reason, FDA has issued a series of regulations that comprehensively dictate the form and substance of all prescription drug labels. Those drug labels must include, among other requirements, "a summary of the essential scientific information needed for safe and effective use of the drug," 21 C.F.R. §201.56(1), including a description of "clinically significant adverse reactions," "other potential safety hazards," "limitations in use imposed by them, ... and steps that should be taken if they occur," *id.* Accordingly, FDA's approval of an application to market a drug is inseparable from the agency's approval of the precise language contained on the drug's label. *See id.* §314.50(e)(2)(ii), (l)(1)(i). Additionally, FDA has the authority to withdraw a drug if it concludes that the drug is unsafe or ineffective for any of its labeled uses. *See* 21 U.S.C. §355(e).

8. There is no provision in the FDCA or in the FDA regulations which would allow a generic drug manufacturer to change its labeling to contain information that is not present in the labeling for the reference listed drug. Drug manufacturers are routinely advised by the FDA that marketing their products with labeling that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug. *See* Letter from FDA to Sidmak Labs approving ANDA for Metoclopramide, [Doc. 191, ex. 5].

9. The Courts consistently have made clear that Congress has safe-guarded FDA's science-based discretionary decisions from second-guessing. *See, e.g., Heckler v. Chancy*, 470 U.S. 821, 835 (1985); *see also Weinberger v. Bentex Pharm., Inc.*, 412 U.S. 645, 653-54 (1973) ("The determination whether a drug is generally recognized as safe and effective ... necessarily implicates complex chemical and pharmacological considerations" and is "peculiarly suited to initial determination by the FDA."); *Nutraceutical Corp. v. Von Eschenbach*, 459 F.3d 1033,

1043 (10th Cir. 2006) (“The review of scientific literature is properly in the province of the FDA, to which this Court grants deference based on its expertise.”); *Schering Corp. v. FDA*, 51 F.3d 390, 399 (3rd Cir. 1995) (“[FDA’s] judgments as to what is required to ascertain the safety and efficacy of drugs fall squarely within the ambit of the FDA’s expertise and merit deference from us.”). As stated above, the FDA’s evaluation of the safety and efficacy of a drug includes an evaluation of the labeling proposed for that drug.

10. In the present case, the FDA “has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.” *Medtronic Inc. v. Lohr*, 518 U.S. 470, 501 (1996). Specifically, the FDA has approved the labeling that accompanied Pliva’s metoclopramide. There is no allegation that Pliva’s label differed from that of the Reference Listed Drug at any time relevant to this matter. The result is that the label is adequate as a matter of law, and Plaintiff cannot recover on any of her claims, as they all arise from the allegation that Pliva’s metoclopramide label was inadequate. An analysis of the other arguments presented in Pliva’s Motion for Summary Judgment is unnecessary, as the adequacy of the label is dispositive of all of Plaintiff’s claims. Pliva’s Motion for Summary Judgment is granted with respect to all of Plaintiff’s claims.

11. With respect to Defendants’ Joint Motion to Dismiss Based on Federal Preemption [Doc. 198], the Court finds that three Federal Circuit Courts of Appeal have dealt with this issue, and have concluded that claims against generic drug manufacturers, such as those asserted in this lawsuit, are not preempted by federal law. *See Foster v. Am. Home Prod. Corp.*, 29 F.3d 165 (4th Cir. 1994); *Mensing v. Wyeth, et al.*, 588 F.3d 603 (8th Cir. 2009). *Demahy v.*

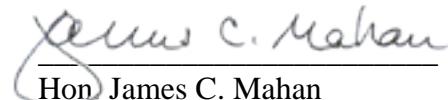
Actavis, Inc., 593 F.3d 428 (5th Cir. 2010). Absent any authority to the contrary, this Court will not go against the weight of authority bearing on the issue. As a result, Plaintiff's claims against Pliva are not preempted by Federal Law, and Pliva's Motion to Dismiss is denied.

12. Finally, Plaintiff's Motion for Partial Summary Judgment seeks a determination by this Court that Pliva had an obligation to assess the risks associated with its metoclopramide product and to ensure that its label remained adequate as long as its drug was on the market. *See generally* Plaintiff's Motion, [Doc. 196]. The Court finds that Plaintiff has failed to establish that, as a matter of law, any alleged breach of a federal regulatory obligation would establish liability under Nevada law, and as a result, the motion is denied.

III. DECISION AND ORDER

Based on the foregoing findings of fact and conclusions of law, it is hereby ORDERED, ADJUDGED and DECREED that (1) Pliva's Motion for Summary Judgment [Doc. 206] is hereby GRANTED and JUDGMENT is entered in favor of Pliva on all claims; (2) Pliva's Motion to Dismiss Based on Federal Preemption [Doc. 198] is DENIED; and (3) Plaintiff's Motion for Partial Summary Judgment [Doc. 196] is DENIED.

IT IS SO ORDERED,



Hon. James C. Mahan
U.S. District Court Judge
Dated: August 23, 2010

Respectfully submitted,

/s/ Terrence J. Donahue, Jr.
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CERTIFICATE OF SERVICE

I hereby certify that on August 20, 2010, I electronically filed the foregoing document with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all Counsel of Record.

s/ Terrence J. Donahue, Jr.